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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,999	02/29/2000	Yoshihiro Tanimoto	KODA20A.001AUS	1582

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/26/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,999

Applicant(s)

Tanimoto et al.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 17, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

The amendment filed 1/17/02 is acknowledged. Claims 2-9 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for “wherein the amount of polyamine dissociated from said yeast somatic components is approximately double or more” as now recited in claim 9. In the specification, at page 10, lines 24 et seq. it is indicated that with the specific procedure of Example 3 it was possible to obtain a yield 3.2 times more than the yield of polyamine composition obtained by a conventional method. The material used is a commercial yeast RNA preparation, the degree of purification and/or processing of which cannot be readily ascertained. Thus, the correlation with “yeast RNA compositions” as claimed is not clearly delineated.

It must be noted that the claim as written has an infinite upper limit and does not indicate how the comparison is intended to be achieved. Also there is no clear correlation between the claim designated “polyamine” obtained by various alternative means in claim 9, and the “polyamine composition” obtained by a specific method from a specific source recited in the cited passage from the specification.

Therefore, this material raises the issue of new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 encompasses an improper Markush grouping because of the improper use of "or" Conjunctive rather than alternative language should be used (e.g. selected from the group consisting of A,B, AND C). The claims as drafted do not follow this form. See MPEP 2173.05(h)(a).

Claim 9 is confusing in that the nature of "a high molecular weight substance" is unclear. Is one high molecular weight substance degraded while others are not?

Claim 9 is vague, indefinite and confusing in the recitation of "approximately double or more". The amount intended cannot be determined with any precision. Also, it is not indicated what the "double" is of.

Claim 9 is vague and indefinite in that the product intended to be recovered is uncertain because of the recitation of "recovering polyamine". Is this a single "polyamine" or is it more than one "polyamine". It is not apparent that "polyamine" is a recognized collective noun. In addition, the claim preamble is directed to a process of making a "polyamine composition".

Claim 4 is confusing in that it is uncertain whether the nuclease treatment occurs at the recited pH range and temperature or whether the solution is submitted to this treatment before or after the nuclease reaction.

Claims 4 and 7 are/remain confusing in the use of the of a wavy line rather than a dash to indicate ranges. Replacement with dashes would be remedial.

Claims 4-5 fail to find clear antecedent basis in claim 9 for a "decomposition step"n extraction process. The step recited is "subjecting". Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter

as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanekawa *et al.*, taken with Sato *et al.*, Ajinomoto and Sugimoto.

Tanekawa *et al.* teaches a method for preparing a polyamine composition wherein yeast somatic components are obtained by hydrolysis using alkali (See, e.g., example 1). In addition, Tanekawa *et al.* disclose further processing of the extract by using a nuclease, such as RNA-decomposing enzymes contained in yeast cells after obtaining the yeast somatic composition (See, e.g. Example 1). The reference discloses the hydrolysis of RNA, a high molecular weight substance which is inherently bound to polyamine. The process was effected at pH 6 and a temperature of 60°C (See, e.g., col. 6, lines 4 et seq.)

The reference differs from the claimed invention in that the recovery of polyamines is not disclosed. However, Sato *et al.* adequately demonstrates that the process of producing an extract containing yeast somatic components produces recoverable amounts of polyamines, wherein the polyamines are recovered after treatment with a 10-30% sodium hydroxide solution for neutralization purposes.

In addition, Ajinomoto teach the use of an accelerator for autolysis to produce a solution of yeast components, which, of course, contain polyamines and Sugimoto *et al.* teach the addition of sodium chloride to yeast to effect lysis and wherein the process occurs at about 100°C and at pH 4. The concentration of sodium chloride and other process parameters appear to be at the required level. However, even if it is not the adjust of conditions identified as result-effective variables cited in the reference would have been prima facie obvious to a person having ordinary skill in the art for optimization purposes.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of obtaining polyamines from yeast

somatic components as disclosed by Tanekawa *et al.* by recovering polyamines as taught by Sato *et al.* and by carrying out the hydrolysis under various process conditions, including the use of salts and/or enzymes as disclosed by Ajinomoto and Sugimoto in view of the expected benefit of obtaining a greater yield of solid matter containing polyamines in the solution as suggested by Sato *et al.* and Tanekawa *et al.* (See, e.g., col. 4, lines 10-12).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanekawa *et al.*, taken with Sato *et al.*, Ajinomoto and Sugimoto as applied to claims 2-5 and 7-9 above, and further in view of Iijima (JP 09117263) and Stanzl *et al.*.

The references differ from the claimed invention in the extraction of yeast somatic components by using crushing in a high pressure homogenizer or sonication. However Iijima teach a process of extraction of yeast somatic components by using crushing in a high pressure homogenizer (See, e.g., Abstract). and Stanzl *et al.* adequately demonstrate the use of ultrasonic disintegration to obtain somatic components from yeasts (See, e.g., Example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Iijima or Stanzl *et al.* according to the teachings of Tanekawa *et al.*, Sato *et al.*, Ajinomoto and Sugimoto discussed above by using crushing in a high pressure homogenizer or sonication as methods of obtaining yeast somatic components from yeast cells.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Contrary to applicants' arguments, the Tanekawa *et al.* reference discloses the treatment of somatic components in a yeast extract with a nuclease at the claim designated process parameters. Even though the reference does not specifically recover the polyamines produced, the claim as written is directed to the production of a polyamine composition and the products

recovered are not purified beyond the nuclease treatment step. The secondary references adequately demonstrate the recovery of polyamines as well as the process parameters as claimed.

With respect to the unexpected results demonstrated in the examples with respect to the comparative examples, the material touted does not relate with any specificity to the claim designated invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

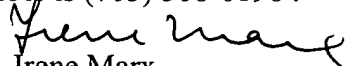
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Irene Marx
Primary Examiner
Art Unit 1651